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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,622	12/21/2000	Curtis Cole	JBP-534	7817

7590 04/21/2004

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/742,622	COLE ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of reply filed on January 23, 2004. Claims 1-23 are pending. Claim rejections and double patenting rejection as indicated in the previous Office action dated October 21, 2003 are maintained for the reasons of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that an acid salt is formed from an amino alkyl alcohol and "a mixture of anionic counterions derived from at least two pharmaceutically acceptable acids and esters thereof". According to the formula of the acid salt shown in applicants' specification, the salt contains only one anionic counterion. The claim is vague and indefinite because the acid salt as claimed cannot be formed as recited, according to the applicants' disclosure.

In response filed on January 23, 2004, applicants argue that "the salt is formed by reacting the desired alkanolamine with a mixture of at least two acids to form a mixture of two salts", and that A denotes a mixture of anionic counterions. Examiner respectfully disagrees that the recited formula in Claim 1 represents mixture of at least two salts because the formula in fact refers to "a compound". See Claim 1, line 3.

The remaining claims are rejected as depending on an indefinite base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (US 4197316). ("Yu").

Yu discloses a method to treat dry skin, including facial skin, using topical composition which comprise one or more alpha hydroxy acids, esters thereof, and their ammonium salts. See abstract; col. 1, lines 16 – 40. See instant claims 13 and 14. Compositions containing ethanolamine salt of glycolic acid, and triethanolamine salt of lactic acid are disclosed. See Examples 1-5. The reference teaches that secondary amines such as N-methylethanolamine and N-ethylethanolamine. See col. 3, lines 14 – 25. A solution containing 2 grams of glycolic acid, 2 grams of citric acid, and ethanolamine is disclosed in Example 5. See instant claim 17. Using malice acid is also suggested. See col. 1, line 60; col. 3, line 30. The Yu reference also teaches that N-ethylethanolamine is a suitable secondary amine for the invention.

Examiner takes the position that the claimed method of improving "the appearance of facial contours" is met because the prior art method is to improve a skin condition.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-11 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 13-17 as above, and further in view of Znaiden et al. (US 5523090) ("Znaiden") and Perricone (US 5554647).

As discussed above, the recited acid salt of alkaloamine is known in the dermatological art. The pH of the solutions of the examples range from 4.4 to 4.7, while the reference generally teaches that the pH of the final composition may range from 3.5-7.5. See instant claims 9 and 20. While the Yu reference fails to expressly teach that the claimed methods of improving "the firmness of skin", and "reducing the appearance of sagging skin", examiner notes that these improvements are associated with treating aging skin. While Yu teaches that malic acid may be used, the reference fails to teach the specific weight ratio of the malic acid and glycolic acid.

Znaiden discloses skin treatment compositions for improving skin strength and firmness, which comprise salts of alpha hydroxy acids and caffeine. The reference teaches that it is well known in the art that alpha hydroxy acids improve "the appearance dry, flaky, wrinkled, aged, photodamaged skin". See col. 2, lines 13 – 20. While a composition containing 1:1 weight ratio of malic acid and lactic acid is disclosed in example 12, the reference fails to teach the specific example of combining malic acid and glycolic acid. The reference, however, teaches that the most preferred acids in the invention include glycolic acid and lactic, and the reference further teaches that the

choice of these alpha hydroxy acid depends on the efficacy of compositions in increasing percutaneous absorption. See col. 5, lines 43 – 45. See instant claim 18.

In general, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is *critical*. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Yu and Znaiden, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation. See instant claim 19.

Perricone teaches that topical application of acetylcholine precursors such as dimethylaminoethanol in a dermatologically acceptable carrier is effective in shortening of muscles, producing increased tone, enhancing the appearance of the skin, and results in a smoother, tighter, and more youthful appearance for aging persons and patients afflicted with conditions that cause sagging faces". See abstract; col. 3, line 36 – col. 4, line 5; col. 8, lines 10-29. See instant claims 10 and 21.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Yu composition by applying the composition to treat dry, flaky, wrinkled, aged, and/or sagging skin as motivated by Znaiden and Perricone, because of an expectation of successfully producing toned, smoother, tighter, and more youthful appearance on the skin. Examiner takes the position that the motivation and the expectation of success is found in the collective teachings of the references that the recited alkaloamines and the alpha hydroxy acids are each well known in treating aged skin conditions.

2. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, Znaiden, and Perricone as applied to claims 1-11 and 13-23 above, and further in view of Quan et al (U.S. Pat. No. 6,180,133 B1) ("Quan").

The combined references fail to teach using the composition with the articles as required by claim 12.

Quan teaches an adhesive, matrix-patch for treating wrinkle. The adhesive contains mixture of vitamins, alpha hydroxy acids or their salts, and glycerine. See col. 3, line 45 – col. 4, line 63; col. 4, lines 44 – col. 5, line 23. The reference teaches that the administration of the composition with the patch system is more effective than by hand, and provides the enhanced absorption of the therapeutic components into the skin. See col. 7, lines 7 – 35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the Yu reference by incorporating the compositions into an adhesive patch, as motivated by Quan, because of expectation to have successfully administered the therapeutic components in the combined references more effectively.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7,10 –12, and 14-16 of copending Application No. 09/677,737. Although the conflicting claims are not identical, both claims are directed to method of using a composition comprising the acid salts of akanolamines having overlapping limitations. The application no. 09/677,737 claims method of ameliorating redness or inflammation of skin, and thus meets the presently claimed method of improving the appearance of facial contour.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments with respect to claims 1-23 have been considered but are not persuasive.

Regarding the § 102 rejection over Yu et al., applicants assert that the reference fails to teach using the prior art composition improve facial contours. Examiner finds applicants' argument unpersuasive because there is no distinction between improving skin conditions such as dry skin which may be facial skin, and improving facial contours. While applicants attempt to limit the prior art method to treat skins other than hands, there is no factual support for applicants' position. It cannot be said that dry condition does not occur in facial skin.

Regarding the § 103 rejection over Yu in view of Znaiden and Perricone, applicants assert that the combined references fail to provide motivation to use the dry skin treatment composition in Yu to improve skin firmness and appearance and to reduce the appearance of sagging skin. Examiner respectfully disagrees, as it is well known in the art that dry skin is associated with aging and sagging skin. See Perricone, col. 1, lines 31 – 58 (stating "treatment of sun-damaged and aged skin consists primarily of application of various creams, lotions and gels to add ***moisture*** to the skin").

Regarding the obviousness rejection made over Yu and Znaiden and further in view of Quan, applicants assert that the method of treating wrinkle in Quan is not related to the teachings of the Yu and Znaiden references. Examiner respectfully disagrees, as the wrinkle treatment certainly is in the same skin cosmetic art as in treating dry and aging skin.

Regarding the double patenting rejection, applicants assert that the methods for ameliorating redness or inflammation of mammalian skin and the methods for ameliorating the irritating effects of a skin irritating composition are somehow different from the claimed methods of improving the appearance of facial contours. Examiner finds the argument unpersuasive because ameliorating redness or inflammation would obviously lead to improvement of the appearance of the skin. Using a skin composition which would eliminating irritating effects would also obviously lead to the improvement of the appearance of the skin.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER